Attachment 5

510(k) Summary

Prepared June 20, 2001

TRADE NAME	TruLine™ Infusion Catheters		
GENERIC NAME	Catheter, Intravascular, Therapeutic, Short-Term		
CLASSIFICATION	Class II (21 CFR 880.5200)		
SUBMITTED BY	Micro Therapeutics, Inc. 2 Goodyear Irvine, CA 92618	**CONTACT**	Eben Gordon Regulatory Affairs (949) 837-3700
PREDICATE DEVICE	MTI Infusion Catheter		
DEVICE DESCRIPTION	The MTI Reinforced Infusion Catheter is a single-lumen plastic catheter designed to be introduced over a guidewire into the vasculature. Once positioned, various pharmacological agents may be delivered through a standard luer lock adapter at the proximal end. The infusion area of the Reinforced Infusion Catheter is indicated by distal and proximal radiopaque markers to facilitate fluoroscopic visualization. The Reinforced Infusion Catheters are available in a variety of infusion lengths.		
INDICATIONS FOR USE	The MTI Reinforced Infusion Catheter is intended to be used for the controlled selective infusion of physician-specified pharmacologic agents or radiopaque contrast media into the general vasculature.		
TESTING	Biocompatibility of the MTI Reinforced Infusion Catheter was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the catheter when tested as an external communicating, blood contact, limited exposure (<24 hrs) device. In-vitro performance testing of the MTI Reinforced Infusion Catheter included dimensional inspection, tensile strength tests, burst pressure tests, flow rate tests, and performance under simulated conditions. All testing of the product yielded acceptable results.		
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The MTI Reinforced Infusion Catheter is substantially equivalent to the predicate device in intended use and principles of operation.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2001

Mr. Eden Gordon
Director of QA/RA
Micro Therapeutics, Incorporated
2 Goodyear
Irvine, California 92618

Re: K011937
Trade/Device Name: Truline Infusion Catheters
Regulation Number: 880.5200
Regulatory Class: II
Product Code: FOZ
Dated: August 9, 2001
Received: August 13, 2001

Dear Mr. Gordon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known): K011937

Device Name: **MTI Reinforced Infusion Catheter**

Indications for Use: **The MTI Reinforced Infusion Catheter is intended to be used for the controlled selective infusion of physician-specified pharmacologic agents or radiopaque contrast media into the general vasculature.**

Rebecca Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011937

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over the Counter Use** _____

(Per 21 CFR 801.109)